Message

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Sent: 10/13/2021 7:08:34 PM
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Subject: Scientists Letter Re: Ending Exemptions to the Premanufacture Notice Process for PFAS
Attachments: Scientists Letter re TSCA PFAS Loopholes.pdf

NOTE: Please see pdf of this scientists letter attached.

Dear Administrator Regan and Assistant Administrator Freedhoff:

We are writing as scientists who have researched or studied the effects of Per- and Polyfluoroalkyl Substances (PFAS). Given the known persistence, bioaccumulation, and toxicity of many PFAS, we are concerned that numerous PFAS have been permitted to enter, and continue to enter, commerce through exemptions to the Toxic Substances Control Act's Pre-Manufacture Notice Process. As a result, we understand that most PFAS entering commerce have not been subject to the full individual safety review set forth in TSCA, and that some PFAS are subject to no review.
For the reasons discussed below, we recommend that EPA grant the petition filed on April 27, 2021, by 15 frontline community and advocacy groups requesting that use of the Low Volume Exemption (LVE), the Low Release and Exposure Exemption (LoREX), the Byproducts Exemption, and the Polymer Exemption be prohibited for PFAS. We further recommend that EPA conduct a full safety review of all PFAS in commerce that previously came to market through one of those exemptions.

I. PFAS Present a Major Public Health Threat

PFAS are a class of widely used industrial chemicals that are problematic due to their high environmental persistence. EPA has identified over 9,000 PFAS but the number of PFAS substances in the environment may be even greater. Because of their persistence, PFAS are ubiquitous in the environment and exposure to multiple PFAS is widespread. People are exposed to PFAS by eating food, drinking water, breathing air, ingesting dust, and through consumer products and food packaging. PFAS are present in the bodies of nearly all people living in the U.S., Europe, and most of the world, including pregnant women and developing fetuses. Several well-studied PFAS are associated with serious health effects, including cancer, thyroid disease, birth defects, hormone disruption, decreased fertility, and immune system suppression, among others, even at low levels of exposure. Subpopulations such as children, developing fetuses, and certain workers experience disproportionate harm from exposure to PFAS. PFAS can reduce the effectiveness of vaccines and emerging evidence suggests that some PFAS exposures may lead to more severe cases of COVID-19.

II. The Environmental Protection Agency's Office of Chemical Safety and Pollution Prevention can play a pivotal role in protecting the public by ensuring that any PFAS manufactured, produced or imported goes or has gone through a full TSCA safety review.

A. PFAS require a thorough safety review

Identifying and remediating PFAS contamination and reducing human PFAS exposure after PFAS have been released to the environment is technically and financially challenging.[1] Thus, ensuring that all new PFAS are subject to a thorough safety review before being brought to market is critical.

1. Cannot Meet "Will Not" Standard

It is our understanding that PFAS are eligible for the LVE, LoREX, and Polymer exemptions only if the scientific evidence demonstrates that PFAS "*will not present* an unreasonable risk of injury to health or the environment," including vulnerable subpopulations. The evidence does not show that PFAS meet such criteria. Based on shared characteristics, such as known persistence, bioaccumulation, and toxicity of well-

studied PFAS, any new PFAS may present unreasonable risk. And because any new PFAS may present unreasonable risk, EPA cannot conclude that PFAS as a class "will not" present an unreasonable risk.

The first reason that PFAS do not meet the "will not" standard is that many PFAS have been shown to be toxic. Numerous studies have demonstrated the toxicity of legacy PFAS,[2] and the more that scientists study newer PFAS, the more we learn of their harm to human health.[3]

A second reason that PFAS do not meet the "will not" standard is that, as a class, PFAS are extremely persistent. Persistence is widely recognized as a hazard criterion in chemical regulatory systems around the world. [4] The high persistence of PFAS will result in increasing concentrations in the environment and in living organisms, increasing exposure for humans, and increasing probabilities of harm. Reversing contamination and reducing harm to our health and environment will take decades, centuries, or even longer.
EPA previously acknowledged that PFAS cannot meet the "will not" standard in an April statement regarding the LVE: "[g]iven the complexity of PFAS chemistry, potential health effects, and their longevity and persistence in the environment, an LVE submission for a PFAS is unlikely to be eligible for this kind of exemption under the regulations."[5]

2. Cannot conduct necessary safety review in 30 days

It is our understanding that PFAS that go through the LVE and LoREX exemptions are subject to a constrained 30-day safety review. This is not adequate time for review of such a complicated topic. To make an assessment of "unreasonable risk" for a new PFAS, EPA must either: 1) comprehensively evaluate exposure, hazard, and relevant susceptibility factors for the new PFAS; or, 2) adopt a "class-based" toxicity assessment approach and rely on existing hazard, exposure, and susceptibility data from PFAS analogues. Under either assessment approach, EPA must also consider that people are exposed to many PFAS and take into account the cumulative risk of exposure to PFAS mixtures. Neither approach would allow EPA to determine within 30 days that a new PFAS will not present an unreasonable risk of injury.

We also understand that if EPA does not complete its assessment of a new PFAS under the LVE or LOREX exemptions within the prescribed 30-day timeframe, the chemical receives an automatic approval to enter into commerce. PFAS are inherently hazardous; it should never be the case that new PFAS are allowed to come to market just because EPA was unable to complete a safety assessment within 30 days.
EPA previously acknowledged that 30 days is insufficient in an April statement regarding the LVE: "Due to the scientific complexities associated with assessing PFAS, and the hazard potential associated with various sub-classes of PFAS, it is challenging to conduct an appropriately robust review of LVE requests for PFAS in the 30 days the regulations allow."5

B. PFAS Byproducts Must Go Through a Safety Review to Protect the Public and the Environment

It is our understanding that EPA does not treat new PFAS byproducts as "new chemicals" under TSCA. Thus, PFAS byproducts have entered and will continue to enter the environment without EPA requiring *any* safety review or approval. We are only aware of this situation because many novel PFAS that are being identified in the environment and in people are byproducts that have never been approved by EPA.
For example, GenX and other ether-containing PFAS were released as byproducts from a Chemours facility on the Cape Fear River in North Carolina for many years. The safety of these chemicals was largely unstudied until Chemours later applied for approval to use GenX as a replacement for PFOA and the chemicals were subsequently detected in drinking water and in people. Because of the byproducts exemption, residents of the Cape Fear region were unknowingly exposed to harmful GenX for years or decades.
Similar contamination incidents have likely occurred in other places and gone undetected. Unless EPA subjects novel PFAS that are produced during the lifecycle of PFAS-containing products to the same rules that govern the assessment of other new chemicals, it will never be able to protect people and the environment from real-world exposures to PFAS.

III. Protecting the Public and the Environment Requires Codified Regulations

Despite unprecedented and growing concern from scientists and the public, the class of PFAS are still largely unregulated. We commend EPA for recognizing the seriousness of the PFAS issue. The informal policy of

discouraging manufacturers from seeking the LVE for new PFAS that was announced this April is a promising first step. However, to protect public health and the environment, regulations are needed for all 4 exemptions at issue in the petition. We recommend granting the petition and conducting a full safety review of all PFAS in commerce that previously came to market through one of those exemptions.

Respectfully Submitted,

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[1]Wang, Z.; DeWitt, J. C.; Higgins, C. P.; Cousins, I. T. A Never-Ending Story of Per- and Polyfluoroalkyl Substances (PFASs)? *Environ. Sci. Technol.* 2017, 51 (5), 2508−2518.

[2]Agency for Toxic Substances and Disease Registry. *Toxicological Profile for Perfluoroalkyls*. (May 2021) https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf

[3]Cheryl Hogue, *Short-chain and long-chain PFAS show similar toxicity, US National Toxicology Program says*, C&EN, (Aug. 24, 2019) https://cen.acs.org/environment/persistent-pollutants/Short-chain-long-chain-PFAS/97/i33.

[4]Cousins, I. T.; Ng, C. A.; Wang, Z.; Scheringer, M. Why is high persistence alone a major cause of concern? *Environmental science. Processes & impacts* 2019, 21 (5), 781−792.

[5]US EPA. *EPA Announces Changes to Prevent Unsafe New PFAS from Entering the Market.* (April 27, 2021) https://www.epa.gov/chemicals-under-tsca/epa-announces-changes-prevent-unsafe-new-pfas-entering-market